REMARKS/ARGUMENTS

Initially, Applicant would like to express appreciation to the Examiner for the detailed Official Action provided.

Applicant also acknowledges with appreciation the indication that claims 8-10 contain allowable subject matter on Page 5 of the Official Action. In this regard, Applicant has rewritten claim 8 into independent form. Thus, Applicant respectfully requests that the Examiner withdraw the objection to claims 8-10 and indicate the allowability of the same.

Upon entry of the above amendments, claim 1, 4 and 8 will have been amended. Claims 1-10 are currently pending. Applicant respectfully requests reconsideration of the outstanding rejections, and allowance of all the claims pending in the present application.

In the Official Action, the Examiner rejected claims 1, 3 and 7 under 35 U.S.C. § 102(b) as being anticipated by SCHMIEDING (U.S. Patent No. 6,270,503).

Without acquiescing to the propriety of the Examiner's rejection, Applicant has amended independent claim 1 solely in order to expedite prosecution of the present application.

In this regard, Applicant submits that SCHMIEDING fails to disclose the combination of elements as recited in claim 1.

In particular, claim 1 sets forth a device for ligament reconstruction including, inter alia, a uniform generally elliptical or generally rectangular cross section which extends perpendicular to a longitudinal axis of the device, and wherein the rear-end is configured to drive the tip and body into a bone which receives ligament reconstruction.

Applicant submits that SCHMIEDING lacks any disclosure of at least the above noted combination of elements.

In setting forth the rejection, the Examiner asserts that SCHMIEDING discloses the presently claimed ligament reconstruction device. More specifically, the Examiner asserts that the device of SCHMIEDING has a generally elliptical (or rectangular) cross section, i.e., "since the cross section could be taken at an angle with respect to the longitudinal axis of the device" (*see*, the last four lines on Page 2 of the Official Action).

Contrary to the Examiner's assertions, Applicant submits that the device of SCHMIEDING is very different structurally from the presently claimed invention.

In particular, Applicant submits that the amended claim 1 of the present invention recites that the generally elliptical or generally rectangular cross section extends perpendicular to a longitudinal axis of the device. Therefore, contrary to the presently claimed invention, Applicant submits that a cross section taken perpendicular to a longitudinal axis of the device of SCHMIEDING is circular in cross section.

Thus, Applicant submits that SCHMIEDING does not disclose at least the presently claimed device having a generally elliptical or generally rectangular cross section extending perpendicular to a longitudinal axis of the device, as generally recited in claim 1.

Applicant further submits that at least one advantage of the presently claimed invention is that the tip and body portion have a generally elliptical or rectangular cross section, rather than a simple round cross section (i.e., as disclosed in SCHMIEDING).

Therefore, Applicant submits that a bone cavity [i.e., formed by using the presently claimed invention] has a cross section close to the cross section of an ordinary

ligament, so that an entire outer peripheral surface of the ligament is brought in proximity to the interior surface of the bone cavity. Hence, the ligament can be bonded to the bone with a greater bonding force in a shorter period of time (see, Page 2, lines 23-29 of the present Specification).

In other words, the presently claimed invention provides a device having a cross section which closely corresponds to the shape of an ordinary ligament, thereby promoting healing in a shorter period of time.

Additionally, Applicant submits that the cross section of the portion of the device 2 which includes guide tunnels 8 does not penetrate the osteochondral flap 80, as shown in Figure 19.

In other words, the single shot guide sleeve 2 is <u>merely</u> used to guide the barrel 92 of an implant gun. Thus, Applicant submit SCHMIEDING does not disclose at least the presently claimed device having a rear-end configured to drive the tip and body into a bone which receives ligament reconstruction, as generally recited in claim 1.

Further, Applicant submits that "[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step." See, In Innova/Pure Water Inc. v. Safari Water Filtration Sys. Inc., 381 F.3d 1111, 1117-20, 72 USPQ2d 1001, 1006-08 (Fed. Cir. 2004).

Accordingly, Applicant respectfully requests that the Examiner clearly explain and indicate <u>how or where</u> SCHMIEDING discloses the rear-end being configured to

drive the tip and connector into a bone which receives ligament reconstruction (as generally recited in amended claim 1) in the next Official Action, i.e., should the Examiner decide to maintain the above-noted basis for rejection.

Accordingly, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. § 102 and allow all pending claims in the present application.

In the Official Action, the Examiner has rejected claims 2 and 4-6 under 35 U.S.C. § 103(a) as being unpatentable over SCHMIEDING.

Applicant respectfully traverses the above noted rejection of claims 2 and 4-6 under 35 U.S.C. § 103(a). Applicant submits that dependent claims 2 and 4-6, are at least patentable due to their dependency from claim 1 for the reasons discussed *supra*. In this regard, Applicant submits that the Examiner has provided no proper reasoning for correcting the above-noted deficiencies in the teachings of SCHMIEDING.

In setting forth the above-noted rejection of claims 2 and 4-6 under 35 U.S.C. § 103(a), the Examiner asserts that the presently claimed ranges (i.e., as recited in claims 2 and 4-6) only involve discovering obvious optimum or workable ranges.

However, Applicant submits that "[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Contrary to the aforementioned standard (i.e., as set forth *In re Antonie*), Applicant submits that the Examiner does not assert and has not provided any factual evidence which reasonably shows that a particular cross sectional range of the device of SCHMIEDING achieves a recognized result.

Applicant further submits that the Examiner's assertion that the combination of elements recited in claims 2 and 4-6, only involve discovering obvious optimum or workable ranges, does not provide any teachings which could reasonably be characterized as curing the above-noted deficiencies in the teachings of SCHMIEDING.

Further, although the Examiner continues to reject the aforementioned claims as being <u>merely</u> a matter of obvious optimization, Applicant submits that the Examiner still has not made such showing, but has relied on a conclusion of obviousness that is not supported by any evidence or reasoning.

In this regard, Applicant submits that the written description clearly discusses the advantages of the present claimed device for ligament reconstruction.

As discussed *supra*, Applicant submits that at least one advantage of the presently claimed invention is that the presently claimed device is configured to form a cavity in which a ligament can be bonded to the bone with a greater bonding force in a shorter period of time (see, the last paragraph beginning on page 2 of the Official Action). Again, contrary to the Examiner's assertions, the applied prior art does not even contemplate the presently claimed cross-section; much less, the advantages associated therewith.

Also, Applicant notes that, in the remarks on page 5 of the Official Action, the Examiner asserts that providing the device with either an elliptical or rectangular cross section are obvious variations, i.e., since Applicant claims the aforementioned cross sections in the alternative.

Contrary to the Examiner's assertions, although Applicant has claimed the aforementioned cross sections in the alternative, both features are independently

patentable over the applied prior art. That is, Applicant submits that the Examiner has not provided any prior art teaching which discloses the presently claimed cross section, i.e., for reasons discussed *supra*.

Thus, Applicant submits that it is apparent from the present Specification that the particular geometries of the device for ligament reconstruction, as recited in claims 2 and 4-6, will at least have an advantageous effect on ligament bonding.

Accordingly, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. § 103 and allow all pending claims in the present application.

Further, if the Examiner decides to maintain the aforementioned rejection of claims 2 and 4-6, Applicant respectfully requests that the Examiner provide an appropriate teaching reference disclosing the recited features.

In view of the arguments herein, Applicant submits that independent claim 1 is in condition for allowance. With regard to dependent claims 2-7, Applicant asserts that they are allowable on their own merit, as well as because of their dependency from independent claim 1, which Applicant has shown to be allowable.

Thus, it is respectfully submitted that all of the claims in the present application are clearly patentable over the references cited by the Examiner, either alone or in combination, and an indication to such effect is respectfully requested, in due course.

SUMMARY

Applicant submits that the present application is in condition for allowance, and respectfully requests an indication to that effect. Applicant has argued the allowability of the claims and pointed out deficiencies of the applied reference. Accordingly, reconsideration of the outstanding Official Action and allowance of the present application and all the claims therein are respectfully requested and is now believed to be appropriate.

Applicant submits that this amendment is being made to advance prosecution of the application to allowance and should not be considered as surrendering equivalents of the territory between the claims prior to the present amendment and the amended claims. Further, no acquiescence as to the propriety of the Examiner's rejection is made by the present amendment. All other amendments to the claims which have been made in this amendment, and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

P29144.A09

Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted, Konsei SHINO

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